Celcuity Announces FDA Acceptance of New Drug Application for Gedatolisib in HR+/HER2-/PIK3CA Wild-Type Advanced Breast Cancer

January 20, 2026

- *FDA grants Priority Review and assigns a PDUFA goal date of July 17, 2026*

MINNEAPOLIS, Jan. 20, 2026 (GLOBE NEWSWIRE) -- Celcuity Inc. (Nasdaq: CELC), a clinical-stage biotechnology company pursuing development of targeted therapies for oncology, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for filing its New Drug Application ("NDA") for gedatolisib in hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), *PIK3CA* wild-type advanced breast cancer ("ABC"). The FDA granted Priority Review and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of July 17, 2026.

The NDA was submitted under the FDA's Real-Time Oncology Review ("RTOR") program, which is intended to facilitate shorter regulatory review periods. Gedatolisib previously received both Breakthrough Therapy and Fast Track designations based on promising preliminary clinical data. The submission is based on clinical data from the *PIK3CA* wild-type cohort of the Phase 3 VIKTORIA-1 clinical trial.

"The FDA's acceptance of our New Drug Application for gedatolisib and the assignment of a PDUFA goal date is a pivotal milestone in our efforts to bring a much-needed new treatment option to patients with HR+/HER2- advanced breast cancer," said Brian Sullivan, CEO and co-founder of Celcuity. "We believe the robust clinical dataset underlying this submission demonstrates the practice changing potential of gedatolisib. We are looking forward to collaborating with the FDA throughout the review process as we work towards a potential approval and commercial launch."

Gedatolisib

Gedatolisib is an investigational, multi-target PI3K/AKT/mTOR ("PAM") inhibitor that potently targets all four Class I PI3K isoforms, mTORC1, and mTORC2 to induce comprehensive blockade of the PAM pathway.[1,2,3] As a multi-target PAM inhibitor, gedatolisib's mechanism of action is highly differentiated from currently approved single-target inhibitors of the PAM pathway.[2] Inhibition of only a single PAM component results in cross-activation of the uninhibited components, which limits the suppression of PAM pathway activity. Gedatolisib's comprehensive PAM pathway inhibition enables full suppression of the PAM pathway by minimizing the adaptive cross-activation that occurs with single-target inhibitors. Unlike single-target inhibitors of the PAM pathway, gedatolisib has demonstrated comparable potency and cytotoxicity in *PIK3CA*-mutant and wild-type breast tumor cells in nonclinical studies and early clinical data.[3,4]

About Celcuity

Celcuity is a clinical-stage biotechnology company pursuing development of targeted therapies for treatment of multiple solid tumor indications. The company's lead therapeutic candidate is gedatolisib, a potent, pan-PI3K and mTORC1/2 inhibitor that comprehensively blockades the PAM pathway. Its mechanism of action and pharmacokinetic properties are differentiated from other currently approved and investigational therapies that target PI3Kα, AKT, or mTORC1 alone or together. A Phase 3 clinical trial, VIKTORIA-1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR+/HER2- ABC, has completed enrollment and the company has reported detailed results for the *PIK3CA* wild-type cohort and has completed enrollment of patients for the *PIK3CA* mutant cohort. A Phase 3 clinical trial, VIKTORIA-2, evaluating gedatolisib plus a CDK4/6 inhibitor and fulvestrant as first-line treatment for patients with HR+/HER2- ABC, is currently enrolling patients. A Phase 1/2 clinical trial, CELC-G-201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, is ongoing. More detailed information about Celcuity's active clinical trials can be found at ClinicalTrials.gov. Celcuity is headquartered in Minneapolis. Further information about Celcuity can be found at www.celcuity.com. Follow us on LinkedIn and X.

Forward-Looking Statements

This press release contains statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the potential therapeutic benefits of gedatolisib; the size, design and timing of our clinical trials; our interpretation of clinical trial data; our expectations regarding the timing of and our ability to obtain FDA approval under the RTOR program and to commercialize gedatolisib; and other expectations with respect to gedatolisib. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should," and "could," and similar expressions or words identify forward-looking statements. The forward-looking statements included in this press release are based on management's current expectations and beliefs which are subject to a number of risks, uncertainties and factors, including that our clinical results are based on an ongoing analysis of key efficacy and safety data and our interpretation of such data may change; unforeseen

delays in the review of our NDA for gedatolisib; and our ability to obtain and maintain regulatory approvals to commercialize gedatolisib. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2024, as such risks may be updated in our subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by these cautionary statements, and we undertake no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

References

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